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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,366	07/24/2000	Cathy Ilyse Hess	D4857-00006	7385

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EXAMINER	
FRENEL, VANEL	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/626,366	Applicant(s) HESS, CATHY ILYSE	
	Examiner Vanel Frenel	Art Unit 3626	MW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Application

1. This communication is in response to the Response filed 01/22/04. Claims 1-17 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,370,511) in view of Hennessy et al (6,277,071), and further in view of Gibson et al (6,077,082), for the same substantially the same reasons given in the previous Office Action (Paper number 11). Further reasons appear hereinbelow.

(A) As per claim 1, Dang and Hennessy disclose a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as data record in said data storage means (See Dang, Col.12, lines 27-67).

monitoring and comparing said recorded clinical actions taken by said clinician to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Dang and Hennessy do not collectively disclose issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway so as to allow said clinician to alter said clinical action.

However, this feature is known in the art, as evidenced by Gibson. In particular, Gibson suggests issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Gibson within the collective teachings of Dang and Hennessy with the motivation of providing a fairly

realistic real-time representation of a doctor–patient relationship which can be generated in software and implemented on a personal computer (See Gibson, Col.1, lines 40-50).

(B) As per claim 2, Hennessy discloses a method according wherein said gathering of said patient care data includes applying a risk assessment tool comprising a rating scale to objectively characterize the subjective condition of said patient's skin and wound (See Hennessy Fig.20; Col.10, lines 29-60).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Hennessy discloses a method according wherein said rating scale identifies factors most closely associated with the formation of a selected malady (Col.2, lines 36-67 to Col.3, line 8).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Hennessy discloses a method wherein said factors are associated with parameters that are identified and assessed by said clinician, and a rating number assigned to each of said parameters that corresponds to said clinician's objective assessment of a wound/skin condition (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(E) As per claim 5, Hennessy discloses a method wherein a finite numerical score is selected from a preselected range and assigned to each of said parameters (Col. 9, lines 29-63).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(F) As per claim 6, Hennessy discloses a method wherein a numerical score at or above a preselected value is indicative of a high risk for development of said malady (Col.9, lines 64-67 to Col.10, line 23).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(G) As per claim 7, Hennessy discloses a method wherein said parameters, along with their assigned scores, are stored at a known, searchable, and retrievable location in said data storage means (Col.9, lines 29-63).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(H) As per claim 8, Hennessy discloses a method wherein said monitoring includes reviewing each of said parameters, and identifying a most likely course of intervention to be followed by said clinician (Col.11, lines 1-45).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(I) As per claim 9, Dang discloses a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means of a general purpose computer as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang,Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as a data record in said data storage means (See Dang, Col.12, lines 27-67).

monitoring and comparing said recorded clinical actions taken by said clinician to said identified clinical pathway so as to identify one or more variations from said

identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Dang does not explicitly disclose issuing an alert notice to said clinician of an identified variation form said identified clinical pathway at the time of performance of said clinical action identified as a variance so as to allow said clinician to alter said clinical action.

However, this feature is known in the art, as evidenced by Gibson. In particular, Gibson suggests issuing an alert notice to said clinician of an identified variation form said identified clinical pathway at the time of performance of said clinical action identified as a variance so as to allow said clinician to alter said clinical action (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Gibson within the collective teachings of Dang and Hennessy with the motivation of providing a fairly realistic real-time representation of a doctor–patient relationship which can be generated in software and implemented on a personal computer (See Gibson, Col.1, lines 40-50).

(J) As per claim 10, Hennessy discloses a method wherein said gathering of said patient care data includes observing and recording a patient's vital signs (Col.7, lines 26-51).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(K) As per claim 11, Hennessy discloses a method wherein said recorded vital signs are each compared to a preselected value for said vital sign and monitored for deviations that are indicative of a high risk for development of a skin malady (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(L) As per claim 12, Hennessy discloses a method wherein said implementing said identified clinical pathway and recording clinical actions taken by said clinician includes implementing a skin and wound care regimen (Col.2, lines 1-35; Col.6, lines 30-67).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(M) As per claim 13, Hennessy discloses a method wherein said skin and wound care regimen are monitored for deviations that are indicative of a high risk for deterioration of said skin and wound (Col.6, lines 12-67).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(N) As per claim 14, Hennessy discloses a method wherein said regimen comprises selection and application of dressings to a wound (See Hennessy Fig.20; Col.6, lines 30- 67).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(O) Claim 15 differs from claims 1 and 9 by reciting a method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data according to a predetermined regimen for diagnosing a malady of the skin; (B) storing said patient care data in a data storage means of a general purpose computer.

As per this limitation, it is noted that Dang discloses (C) identifying an appropriate clinical pathway from a plurality of pathways for treating said diagnosed malady (Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway via clinical actions taken by a clinician (Col.12, lines 27-67) and Hennessy discloses monitoring said clinical actions taken by said clinician to determine variations from said identified clinical pathway (See Hennessy, Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56); and Gibson discloses issuing an alert notice to said clinician of an identified variation from said identified clinical pathway at the time of performance of said clinical

action identified as a variance so as to allow said clinician to alter said clinical action (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

Thus, it is readily apparent that these prior art systems utilize a predetermined regimen to perform their specified function.

The remainder of claim 15 is rejected for the same reason given above for claims 1 and 9, and incorporated herein.

(P) As per claim 16, Hennessy discloses a method wherein said regimen comprises answering a questionnaire that quantifies a patient's satisfaction with his/her health status (See Hennessy Col.2, lines 8-35).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 15, and incorporated herein.

(Q) As per claim 17, Dang discloses disclose a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as data record in said data storage means (See Dang, Col.12, lines 27-67).

monitoring and comparing said recorded clinical actions taken by said clinician, while said clinician is treating said patient, to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Dang and Hennessy do not collectively disclose issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway so as to allow said clinician to alter said clinical action.

However, this feature is known in the art, as evidenced by Gibson. In particular, Gibson suggests issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Gibson within the collective teachings of Dang and Hennessy with the motivation of providing a fairly

realistic real-time representation of a doctor–patient relationship which can be generated in software and implemented on a personal computer (See Gibson, Col.1, lines 40-50).

Response to Arguments

4. Applicant's arguments filed on 01/22/04 regarding claims 1-17 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed on 01/22/04.

(A) At page 9-116 of the 01/22/04 response, Applicant's argues the followings:

(1) Neither Dang nor Hennessy alone or in any valid combination provide or suggest such a methodology, and neither provide the requisite motivation to combine them as the Examiner has done, absent impermissible hindsight.

(2) Gibson does not teach or suggest issuing an "alert notice" or alarm or any kind.

(3) There is nothing in the disclosure of Dang, Hennessy, or Gibson collectively which is remotely related to either (i) accessing and documenting and skin conditions; or (ii) automatically triggering an alerting mechanism that is activated, in real-time, when a treatment is initiated on a living, breathing patient by a treating physician, which treatment deviates from an expected or standard treatment under the then current clinical circumstances.

(4) The combined teachings of the Dang, Hennessy, and Gibson references are not properly combinable.

(5) The prior art references identified by the Examiner as pertinent and determined that none of them, alone, or in any valid combination with the Dang, Hennessy or Gibson references anticipates or renders obvious the present invention.

(B) With respect to Applicant's first argument that the Examiner's motivation to combine is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such as reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

(C) With respect to Applicant's second argument, Examiner respectfully submits that Gibson discloses "Since the simulation is run on a continuing basis, a patient may require attention at any time. Verbal and visual queues that the patient requires attention may be presented by employing the display 20 and speakers 22. Further, the monitoring system may trigger the pager transmitter 48 if the user fails to respond to the verbal and visual queues within a predetermined of time. The transmitter activates the pager device 46 that the user carries when away from the simulation display" which correspond to Applicant's claimed feature (See Gibson, Col.4, lines 35-49). Therefore, Applicant's argument is not persuasive.

(D) With respect to Applicant's third argument, Examiner respectfully submits Hennessy suggests "Referring to FIG. 1, a chronic disease monitor in accordance with a preferred embodiment is generally shown at 10. Chronic disease monitor 10 includes a central database 12 that electronically stores chronic disease information and enables a system user to access the stored information to monitor a chronic disease. Central database 12 includes computer memory in the form of RAM and ROM memory and is located in the computer hardware or deposited on a readable storage media. Guideline 14 comprises an algorithm representing known parameters of a chronic disease, including risk factors and complications associated with that disease, may be tailored by the medical provider to implement a facility wide treatment plan to a given patient population as well as on an individual patient basis. Patient record 16 information, such as demographic information 100 and insurance information 102, is inputted by user at user terminal 18, such as a computer terminal, a personal computer interfaced within a local area network, and the like. Site information 17 comprises data associated with the location of the installation (e.g. location, licensee, etc.). Patient information 16 is updated in a variety of ways. For example, a user may enter progress notes and/or test results at user terminal 18. Meter device 20, such as a blood glucose monitor, may provide test results in electronic data form. Processor 22 comprises a central processing unit, such as a microprocessor, which stores and accesses the information in central database 12 (such as a patient record 16). Database interface 13 comprises a plurality of operating systems and programs allowing monitor 10 to store and retrieve

data stored in database 12. Patient record 16 is applied to an algorithm within guideline 14. If a test result exceeds an expected threshold, an alert is generated and a notation is stored in risk manager 24. The alert may be communicated to an off site location 26, e.g. via e-mail 27, such as to an employer, health maintenance organization and the like, and/or a letter may be printed to the patient via printer 28. Additionally, if a patient fails to attend a scheduled service, an alert is similarly generated. Processor 22 may optionally be linked to a central database 29 (offsite) via a TCP/1P link as is known in the art. Provider information 30 (e.g., a physician) and health plan information 32 are also stored in central data base 12, to enable communication with medical providers and third parties. While the chronic disease monitor of the present invention may be used for other chronic diseases, chronic disease monitor 10 is particularly relevant with respect to diabetes and therefore, hereinafter, the chronic disease monitor will be described with respect to the monitoring and control of diabetes.

Referring now to FIG. 2, patient record information 16 is generally shown in block diagram form and is described as follows. Monitor 10 incorporates a window format and is programed in Microsoft Visual Basic to operate in an Windows environment. It will be appreciated by those of ordinary skill in the art that other programing formats and/or languages may be employed. Patient record 16 is entered by a user at user terminal 18 and includes the patient's demographic information 100 e.g., salutation, name, gender, year of diagnosis, diabetes type (type 1, type 2, gestational), address, contact information (e-mail, work and home phone), initiation of care date, health plan, health plan id, provider, employer and language. Insurance information 102 is also recorded in

patient record 16. An identifying number for the patient is stored in the data base. Additionally, complications, risk factors/co-morbid conditions 104 such as retinopathy, neuropathy, nephropathy, PVD, CAD and cerebral vascular disease are recorded. Patient record 16 also include test data 106. Test data 106 comprises the office visit date, practitioner, office visit comments, such as progress notes and patient concerns, are recorded. Clinical information, i.e. weight, height, blood pressure, smoking status, blood glucose recordations (SMBG), lipids profile, liver enzyme, foot exams, neuropathy, skin condition, eye exam, are stored. It will be appreciated to those skilled in the art, the blood glucose information may be entered manually or electronically transferred from a blood glucose metering device 20, such as a Life Scan OneTouch. Data may also be transferred directly from a laboratory, such as via an RS-232 port or TCP/1P (FIG. 1) in HL7 (or other standard data format). Quality of life indicators, such as number of emergency room visits, days of hospitalization, days lost from work, and activities, provide important outcome information. By storing this information in patient record 16, reports may be generated comparing changes in these factors over a given period of time and/or for a selected treatment therapy. Combinations may be applied. Further, a patient's own self assessment is recorded as diabetes is such that success in treatment is heavily dependant on the patient's active participation.

Patient record 16 also includes a quality plan 110. Monitor 10 generates quality plan 110 from a selected guideline 14 and allows the user to customize the quality plan by selecting frequencies, thresholds and goals for a series of tests which are required to be performed on the patient, setting alert values if thresholds are exceeded or if tests are

not undertaken. For example, tests for HbAlc, lipids (to measure cholesterol), blood protein (microalbumin), eye and foot examinations are recommended by the American Diabetes Association. As described in greater detail below, the frequencies for these examinations are defaulted to the recommended ADA values (but may be over-written by the user). Additional tests may be programmed, such as a stress test for cardiovascular disease. The frequency of office visits may be stored. Monitor 10 notifies providers, health care plans and patients via letters, e-mail, etc. Letters may be stored in the form of reminders, and/or report letters, indicating test results, a missed appointment, an alert and the like. Patient services 108 including self-education, nutrition counseling, smoking cessation, patient satisfaction, flu vaccine and pneumonia vaccine are also stored in patient record 16. Patient record 16 also includes a patient's medications, therapies and treatments (such as medication, dosage, frequency start date, a nutrition plan and exercise plan)" which correspond to Applicant's claimed feature (See Hennessy, Col.5, lines 30-67 to Col.6, line 67; Col.7, lines 1-8). Therefore, Applicant's argument is not persuasive.

(E) With respect to Applicant's fourth and fifth arguments, Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685,686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143,147 (CCPA

1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a *prima facie* case of obviousness, since he has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Applicant's claimed invention (see paper number 11). Moreover, in the instant case, the Examiner respectfully notes that each and every motivation to combine the applied references are accompanied by select portions of the respective reference(s) which specifically support that particular motivation and/or an explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness. As such, it is NOT seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner, *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

In addition, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, Applicant's argument is not persuasive.

In response, all of the limitations which Applicant disputes as missing in the applied references of the 01/22/04 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Dang, Hennessy and/or Gibson based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (paper number 11), and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches three step wound treatment method and dressing therefor (4,813,942), system and method for managing patient medical records (5,772,585), medical system and associated method for automatic treatment (5,544,651) and skin patch for use in contact immunotherapy (5,846,559).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

V.F
V.F

April 3, 2004

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600